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EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
09/13/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,326	GRONTHOS ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE T. HIRIYANNA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2011*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *172,175-181,184-186 and 191-196* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *172,175-181, 184-186, and 191-196* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/20/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on *06/20/2011* in response to office action mailed on 01/19/2011 has been acknowledged.

Claims 172,176 and 192 are amended.

Claims 131-171, 173,174, 182, 183, and187-190 were previously canceled.

Claims 195 and 196 are new.

Claims 172,175-181, 184-186, and 191-196 *are pending and are examined in this office action. Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300. The Affidavits, IDS submitted with the response of 06/20/2011are fully considered.*

Withdrawn: Claims 172,175, 176, 184 and 193 rejections under 102(b) as being anticipated by Reyes et al (2002, Clin. Invest. 109:337-346) for the reasons of record as set forth in the Office Action mailed on 01/19/2011 is withdrawn in view of Applicants arguments.

Withdrawn: Claims 172,175, 176, 184, 191, and 193-196 are rejected under 102(b) as being anticipated by Kocher et al., (2001, Nature Medicine 7:430-436) for the reasons of record as set forth in the Office Action mailed on 01/19/2011 is withdrawn in view of Applicants arguments.

Withdrawn: Claims 172,175, 176, 183, 184, 191, and 193-194 rejections under 103(a) as being unpatentable over the prior art cited for the reasons of record as set forth in the Office Action mailed on 01/19/2011 is withdrawn in view of Applicants arguments and in view of the revised rejections below addressing the instant amendments.

Withdrawn: Claims rejections under 112 2nd paragraph as set forth in the Office Action mailed on 01/19/2011 is withdrawn for claims for which the amendments overcome the rejection Applicants arguments are found not persuasive for the claims for which the rejections are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 175, 176, 180, 181, and 192 and dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 175 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out and distinctly claim the subject matter which applicant regards as the invention. The claim recitation on lines 2-3 "0.01% MPCs capable of forming clonogenic colony" implies that the broader claim or the base claim (claim 172) encompasses compositions in which MPCs are incapable of forming clonogenic colonies. Is it so? Applicant should clarify and amend the claim appropriately

Claim 176 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out and distinctly claim the subject matter which applicant regards as the invention. The claim recitation on lines 2-3 "0.01% capable of forming clonogenic colony" implies that the broader claim or the base claim (claim 172) encompasses compositions in which MPCs are incapable of forming clonogenic colonies. Is it so? Applicant should clarify and amend the claim appropriately.

Claims 180, 181 and 192 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out and distinctly claim the subject matter which applicant regards as the invention. The claim recitation of the cells as expressing "one or more markers" "additional markers" "but not limited to" ...etc., imply that base claim is presenting the markers in broader context. However the Applicant has not described the broader genera of cells of the broader claims or base claims, without said markers. Applicant should clarify the same and amend the claim appropriately.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a

foreign country, before the invention thereof by the applicant for a patent.
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 172,175, 176, 184 and 193-196 are rejected under 102(a) as being anticipated by Al-Khaldi et al., (2003, Ann. Thoraic. Surg. 75:204-209; art of record).

The above The claims are drawn to a method of inducing formation or repair of blood vessels comprising contacting a tissue in need of blood vessel repair with a population of cells enriched for mesenchymal precursor cells (MPCs) that express the marker STRO-1 or are the progeny of the MPCs that express the marker STRO-1 so as to thereby generate new blood vessels or repairing blood vessels. In further limitations the cells comprises at least 0.01% cells capable of forming a clonogenic colony, express STRO-1 marker, are mesenchymal precursor cells (MPCs) that comprise additional markers 3G5, MUC18/CD46 and/or alpha smooth muscle actin and/or negative for certain other markers, derived from several different tissue sources, isolated from different niches from a tissue and preferably from perivascular niche and enriched to different extent with respect to cells possessing said markers.

Al-khaldi teaches a method of promoting or inducing angiogenesis using autologous marrow stromal cells (mesenchymal progenitor cells) in a hind limb ischemia of a rat (entire article; abstract; p.204). Al-khaldi teaches systemic administration of $5X10^6$ said cells into anteromedial muscle compartment by injection and observed increased angiogenesis and blood flow (abstract; p.205, col.1-2 bridging p.206; Fig.2-6). Al-Khaldi concludes that MSC or/MPCs could be used as therapy to promote angiogenesis as further evidenced by his demonstration using the rat model (p.208-209). Unless reasons to believe otherwise all or some of the Al-Khaldi's MPCs did express Stro-1 and other markers of MPCs claimed or they are the progeny of the MPCs that express the marker STRO-1. Thus the rejected claims are within the scope of the Al-Khaldi's disclosure.

Claims 172,175, 176, 184, 191, and 193-196 are rejected under 102(b) as being anticipated by Dennis et al (2002, Cells Tissues Organs 170:73-82; art of record).

The above The claims are drawn to a method of inducing formation or repair of blood vessels comprising contacting a tissue in need of blood vessel repair with a population of cells enriched for mesenchymal precursor cells (MPCs) that express the marker STRO-1 or are the progeny of the MPCs that express the marker STRO-1 so as to thereby generate new blood vessels or repairing blood vessels. In further limitations the cells comprises at least 0.01% cells capable of forming a clonogenic colony, express STRO-1 marker, are mesenchymal precursor cells (MPCs) that comprise additional markers 3G5, MUC18/CD46 and/or alpha smooth muscle actin and/or negative for certain other markers, derived from several different tissue sources, isolated from different niches from a tissue and preferably from perivascular niche and enriched to different extent with respect to cells possessing said markers.

Dennis teaches a method of repairing vascular tissue with hematopioesis supportive stromal cells with a vascular smooth muscle-like phenotype and bearing Stro-1 marker (entire article; abstract; p.74-75; p.81, col.2). Dennis further teaches that human bone marrow derived STRO1+ cells differentiate into multiple phenotypes including vascular smooth muscle cells (Abstract, p.74). Dennis further teaches expression of markers like CD10 and CD13, cell adhesion molecules, alpha smooth muscle actin, integrins etc (p.81, col.1). Dennis still further teaches using the above cells for the repair of various mesenchymal tissues. Unless reasons to believe otherwise these cells or the progeny of said cells that express the marker STRO-1induce vascular tissues in the tissues administered. Thus the rejected claims are within the scope of Dennis's disclosure.

Claims 172,175, 176, 184, 191, and 193-196 are rejected under 102(b) as being anticipated by Simmons et al (WO 01/04268 A1).

The above The claims are drawn to a method of inducing formation or repair of blood vessels comprising contacting a tissue in need of blood vessel repair with a population of cells enriched for mesenchymal precursor cells (MPCs) that express the marker STRO-1 or are the progeny of the MPCs that express the marker STRO-1 so as

to thereby generate new blood vessels or repairing blood vessels. In further limitations the cells comprises at least 0.01% cells capable of forming a clonogenic colony, express STRO-1 marker, are mesenchymal precursor cells (MPCs) that comprise additional markers 3G5, MUC18/CD46 and/or alpha smooth muscle actin and/or negative for certain other markers, derived from several different tissue sources, isolated from different niches from a tissue and preferably from perivascular niche and enriched to different extent with respect to cells possessing said markers.

WO 01/04268 A1 teaches MPCs with all the claimed markers of the instant invention and further claims the use of these MPCs for cell therapies of various tissues (entire article; abstract). Unless reason to believe otherwise these MPC's or the progeny of said MPCs that express the marker STRO-1 or the progeny of the MPCs that express the marker STRO-1 induced angiogenesis in the target tissues. Thus the rejected claims are within the scope of the WO 01/04268 A1's disclosure.

Claims 172,175, 176, 184 and 193-196 are rejected under 102(b) as being anticipated by Chopp et al., (2002, The Lancet Neurology 1:92-100; art of record).

The above claims are drawn to a method of inducing formation or repair of blood vessels comprising contacting a tissue in need of blood vessel repair with a population of cells enriched for mesenchymal precursor cells (MPCs) that express the marker STRO-1 or are the progeny of the MPCs that express the marker STRO-1, so as to thereby generate new blood vessels or repairing blood vessels. In further limitations the cells comprises at least 0.01% cells capable of forming a clonogenic colony, express STRO-1 marker, are mesenchymal precursor cells (MPCs) that comprise additional markers 3G5, MUC18/CD46 and/or alpha smooth muscle actin and/or negative for certain other markers, derived from several different tissue sources, isolated from different niches from a tissue and preferably from perivascular niche and enriched to different extent with respect to cells possessing said markers.

Chopp teaches a method of promoting angiogenesis during a treatment of neural injury with bone marrow stromal cells including following in vivo and systemic administration of said cell in rats (entire article; abstract; p.93, col.1 2nd paragraph bridging col.2). Chopp further teaches direct implantation, injection as well as systemic

administration of said cells including intravenous delivery and effect the recovery from pathological process by regenerative angiognesis, vasculogenesis (Abstract; p.96-98; Fig.3). Unless reasons to believe otherwise some or all of Chopp's MPCs (MSCs) express the Stro-1 marker or are the progeny of said MPCs (that express the marker STRO-1). Thus the rejected claims are within the scope of the Chopp's disclosure.

Claims 172,175, 176, 184 and 193-196 are rejected under 102(b) as being anticipated by Bianco et al (2001, Stem cells 19:180-192; art of record),

The above The claims are drawn to a method of inducing formation or repair of blood vessels comprising contacting a tissue in need of blood vessel repair with a population of cells enriched for mesenchymal precursor cells (MPCs) that express the marker STRO-1 or are the progeny of the MPCs that express the marker STRO-1 so as to thereby generate new blood vessels or repairing blood vessels. In further limitations the cells comprises at least 0.01% cells capable of forming a clonogenic colony, express STRO-1 marker, are mesenchymal precursor cells (MPCs) that comprise additional markers 3G5, MUC18/CD46 and/or alpha smooth muscle actin and/or negative for certain other markers, derived from several different tissue sources, isolated from different niches from a tissue and preferably from perivascular niche and enriched to different extent with respect to cells possessing said markers.

Bianco teaches bone marrow stromal stem cells and their potential applications as the components of the vascular wall (entire article; abstract). Bianco further teaches CFU-F fraction derived bone marrow cells (which are enriched in Stro1+ cells) and their potential to differentiate into vascular cells (entire article abstract; p.181-184). Bianco further teaches localization and isolation of Stro-1 bright cells fraction (p.182, co.1-2 bridging p.183-184) and teach that isolated stro-1 bright cells exhibit several endothelial markers (p.185, col.2, 2nd paragraph). Thus the rejected claims are within the scope of the Bianco's disclosure.

Response to Applicants Arguments in the Response of *06/20/2011*:

The Applicants amends to broaden the claims include all the progeny of said MPC expressing Stro-1 marker and argues that the instant invention is not anticipated

by Chopp, Alkahaldi, Bianco, Simmons, Dennis reference which teaches neovascularization or blood vessel repair with bone marrow cells enriched for the stromal cells or MPCs with Stro 1 marker or their progeny.

The Applicants arguments are however found not persuasive. The prior art references of Chopp et al, Al-khaldi do anticipate the invention as they utilize total stromal cells which inherently contained at least a small fraction of MPCs which were Stro1 positive as revealed in the instant invention and the prior art that Stro 1+ MPCs were indeed obtained from stromal cells of the bone marrow and further they do not teach away from Stro-1 cells. Prior art of Dennis et al., Simmons et al, Jones et al, and Bianco et al clearly teach stromal cells comprising Stro 1+ cells and or CFU-F progeny. Further they teach that these cells are capable of inducing vascularization and hence are capable of repairing vascular tissue and/or myocardium. Hence they all anticipate the invention as instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 172,175-181, 184-186, and 191-196 are rejected under 103(c) as being unpatentable over Bianco et al (2001, Stem cells 19:180-192; art of record), Shi et al, 2002 September (J. Bone and Mineral Research Vo.17 (Suppl 1) Page S446; art of record) and Simmons et al (WO 01/04268 A1; art of record), in view of Jones et al (2002, Arthritis and Rheumatism 46:3349-3360; art of record), Dennis et al (2002, Cells Tissues Organs 170:73-82; art of record) and Kocher et al., (2001, Nature Medicine 7:430-436; art of record) .

The above The claims are drawn to a method of inducing formation or repair of blood vessels comprising contacting a tissue in need of blood vessel repair with a population of cells enriched for mesenchymal precursor cells (MPCs) that express the

marker STRO-1 or are the progeny of the MPCs that express the marker STRO-1 so as to thereby generate new blood vessels or repairing blood vessels. In further limitations the cells comprises at least 0.01% cells capable of forming a clonogenic colony, express STRO-1 marker, are mesenchymal precursor cells (MPCs) that comprise additional markers 3G5, MUC18/CD46 and/or alpha smooth muscle actin and/or negative for certain other markers, derived from several different tissue sources, isolated from different niches from a tissue and preferably from perivascular niche and enriched to different extent with respect to cells possessing said markers.

Bianco teaches bone marrow stromal stem cells and their potential applications as the components of the vascular wall (entire article; abstract). Bianco further teaches CFU-F fraction derived bone marrow cells (which are enriched in Stro1+ cells) and their potential to differentiate into vascular cells (entire article abstract; p.181-184). Bianco further teaches localization and isolation of Stro-1 bright cells fraction (p.182, co.1-2 bridging p.183-184) and teach that isolated stro-1 bright cells exhibit several endothelial markers and induce vascularization (p.184, p.185, col.2, 2nd paragraph).

Regarding claims Shi teaches perivascular niche of post natal mesenchymal stem cells in human bone marrow and dental pulp. Shi teaches that these stromal stem cells express smooth muscle antigens and pericyte markers alpha actin and CD146 in addition to STRO-1. DPSCs were additionally found to express 3G5 pericyte marker. Shi however, does not teach inducing formation or repair of blood vessels using said Stro-1 positive cells.

WO 01/04268 A1 teaches MPCs with all the claimed markers of the instant invention and further claims the use of these MPCs for cell therapies of various tissues (entire article; abstract).

Jones teaches regarding the limitations of various markers on the MSCs (MPCs) in claims 180 and 181. In addition to Stro-1+ (Abstract; p3350, col.1, 2nd paragraph) cells further possess various markers including CD29, CD10, CD13 and were negative for CD34. Jones further teaches regarding expanding these cells in culture and clonal assays (entire article; p.3350, col.1, 3rd paragraph; col.2 2nd paragraph).

Dennis teaches a method of repairing vascular tissue with hematopioesis supportive stromal cells with a vascular smooth muscle-like phenotype and bearing Stro-1 marker (entire article; abstract; p.74-75; p.81, col.2). Dennis further teaches that human bone marrow derived STRO1+ cells differentiate into multiple phenotypes including vascular smooth muscle cells (Abstract, p.74). Dennis further teaches expression of markers like CD10 and CD13, cell adhesion molecules, alpha smooth muscle actin, integrins etc (p.81, col.1).

Kocher teaches a method of inducing angiogenesis or neovascularization of ischemic myocardium by human bone marrow derived angioblasts (MPCs) that act as endothelial precursors and improves cardiac function. Unless reasons to believe other wise Kochers MPCs did express Stro-1 and other markers of MPCs claimed.

Regarding claim limitations of using said MPCs or MSCs at various level of enrichment in claims 175-179 and 191 It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Further regarding various markers claimed for the MPCs/MSCs and their niche in a tissue (such as bone marrow peri-vascular niche etc) in claims 184-186 Dennis, Bianco, Jones and WO 01/04268 and Kocher teach all the further claim limitations, and still further the Applicant should note Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. "When the PTO shows a sound basis for believing that the products of the

applicant and the prior art are the same, the applicant has the burden of showing that they are not. Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product.

Thus it would have been obvious for one of ordinary skill in the art to incorporate into the method for promoting angiogenesis in an organ or tissue Stro -1 positive cells for cell therapy as taught by Shi et al and Simmons et al and further supported by the observations of Jones, Dennis and/or Bianco on these MPCS and induce neovascularization or vascular repair of a tissue or the myocardium and induce vascularization.. One of ordinary skill in the art would have been motivated to use Stro-1+ cell enriched MPCs in order to induce angiogenesis or neo-vascualrization as it would promotes healing of the affected organ by relieving from ischemia by increasing blood circulation. One of ordinary skill in the art would have a reasonable expectation of success in making and using enriched Stro 1+ or stro-1+ bright MPCs for inducing neovascualrization because the art teaches that it is routine to transplant MPCs to a tissue and obtain neovascularization, it is routine to make MPCs enriched in Stro1+ or stro-1+ bright cells and art further teaches regarding their potential to differentiate into vascular cells. Thus, the claimed invention was prima facie obvious.

Response to Applicants Arguments in the Response of *06/20/2011*:

The Applicants amends to broaden the claims and still argues that the instant invention is not obvious because the prior art reference which teaches neovascularization or vascular repair with bone marrow derived MPCs does not teach comprising or enriched with Stro1+ cells and/or the prior art which teaches Stro 1+ cells do not teach using them in inducing vascularization or vascular repair.

The Applicants arguments are however found not persuasive. The Applicant first should note that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for

an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art."

The prior art references of Shi et al, Dennis et al, Simmons et al, Jones et al, Bianco et al clearly teach that CFU-F fraction of BM cells clearly are enriched in cell comprising Stro 1+ cells and Kocher et al clear teaches administration same cells or their progeny for inducing vascularization in cardiac tissue. Further these cited references teach that these cells are part of vascular tissue in vivo and are capable of inducing vascularization in vivo and/or the progenitors of vascular tissue cells that are capable of repairing vascular tissue and myocardium. Further the supporting art of Jones and Simmons clearly teach enrichment of Stro 1+cells in BM derived MPCs. Thus the above references make the invention obvious when combined in the light further knowledge available in the prior art. Hence, the invention as claimed was obvious to one of skill in the art at the time of instant invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 172, 175-181, 184-186, and 191-196 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 131-133, 144, 148-151, 154-158, 161-165 of Application No. 11/326,736.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim because the examined claim is either anticipated by, or would have been obvious over, the reference claim.

Instant claims are drawn to a method of administering to a subject's target tissue including cardiac tissue (claim 193) a population of cells enriched for mesenchymal precursor cells (MPCs) that express the marker STRO-1 or their progeny and that includes cardiac tissue . In further limitations the cells comprises at least 0.01% cells that express STRO-1 markers, are positive for 3G5, MUC18/CD46 and/or alpha smooth muscle actin, are positive for additional markers selected from the Markush group of markers recited in claim 140, and/or negative for certain other markers (claim 141), derived from several different tissue sources, isolated from different niches from a tissue and preferably from perivascular niche and enriched to different extent with respect to cells possessing said markers, or are administered differently. The cited claims of '6736 Application are drawn to a method of improving cardiac function in a subject comprising administering to the myocardium or coronary arteries of the subject a population of cells enriched for mesenchymal precursor cells (MPCs) that express the marker STRO-1. In further limitations the cells comprises at least 0.01% cells that express STRO-1 markers, are positive for 3G5, MUC18/CD46 and/or alpha smooth muscle actin, are positive for additional markers selected from the Markush group of markers recited in claim 140, and/or negative for certain other markers (claim 141), derived from several different tissue sources, isolated from different niches from a tissue and preferably from perivascular niche and enriched to different extent with respect to cells possessing said markers, or are administered differently. Accordingly, the claimed process in the present application and the cited patent are obvious variants. Therefore, the inventions as claimed are co-extensive. This is provisional obviousness double patenting rejection.

This is provisional obviousness double patenting rejection since the cited claims have not yet been patented.

Conclusion

No claim allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.,* whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.,* may be reached at **(571) 272-0739.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/ROBERT M KELLY/

Primary Examiner, Art Unit 1633